

Remarks

Reconsideration is respectfully requested in light of the amendments above and the remarks that follow.

Claims 1-24 and 27-30 are pending. Claims 25 and 26 are cancelled. Claims 11-13, 16, and 29 have been amended. The subject matter of claims 25 and 26 has been included in claims 11 and 12, as amended. Additionally, support for amended claims 11-13, 16, and 29 can be found in, for example, pages 13, 20-21, and 24 and claims 11-13, 16, and 29 of the specification as filed.

Claims 1-10, 14-15, 17-24, 27-28, and 30 are withdrawn by the Examiner as directed to non-elected inventions pursuant to 37 C.F.R. § 1.142(b). The election was previously made without traverse.

The Examiner's comments relating to priority under 35 U.S.C. § 119(e) are noted.

Claims 11 and 12 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention. Applicants respectfully traverse.

Claims 11 and 12 have been amended to delete reference to "related diseases" and of "disorders of one or more substances", the sole terms objected to by the Examiner.

In light of the amendments, withdrawal of the rejection is respectfully requested.

Claims 11-13, 16, 25-26 and 29 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Applicants respectfully traverse.

Claims 11 and 12 have been amended to address certain points raised by the Examiner.

The Examiner's position relative to the screening methods is not entirely appreciated. Screening is very much a trial and error process involving large amounts of trial and error experimentation. Here the compound group to be screened is defined. The candidate compounds

either possess modulator activity relative to the claimed reference systems or not. Conventional measuring methodologies are employed.

The methods are described on pages 24 and 25 of the specification. The descriptions there reference "Example (v) and Figure 18" and "Example (vi) and Figure 19", respectively. The Examples are working examples. The identified Figures are experimental results.

It is not apparent from the Office Action why these methods and results do not represent to one of skill in the art that Applicants were in possession of "the subject matter which applicant regards as the invention".

Much of what the Examiner opines on is more relevant to scope of enablement issues, which Applicants address below.

It is Applicants' opinion that a proper *prima facie* case has not been established as to the amended claims. Withdrawal or modification of the rejection is respectfully requested.

Claims 11-13, 16, 25-26 and 29 are rejected under 35 U.S.C. § 112, first paragraph, because while the specification may be enabling for a method of screening for a modulator of SULT4A1 activity in an isolated cell or using a SULT4A1 transgenic or SULT4A1 gene disrupted Drosophila or mouse, the specification does not enable modulation of any SULT4A1 variants by using any methods.

Claims 11 and 12 have been amended. As amended the substances to be screened are limited to those substances associated with Alzheimer's disease and those also expected to modulate the enumerated substances (i)-(iv). The use of "control cell" and test "cell" systems is a conventional approach. The invention resides more in the claimed substances (i)-(iv) and their relation to Alzheimer's disease. Screening is by nature an empirical process that requires trial and error experimentation. Some compounds will have the desired activity, and some will not. The detection methods used are conventional.

Therefore, Applicants do not see that the practice of the invention as now claimed represents undue experimentation.

Applicants maintain that a representative number of variants are described in the specification of the instant application to support the scope of claims 11-13 encompassing "variants" of "(i) a gene coding for a cytosolic sulfotransferase family 4A member 1", "(ii) a transcription product of a gene coding for a cytosolic sulfotransferase family 4A member 1", and "(iii) a translation product of a gene coding for a cytosolic sulfotransferase family 4A member 1". The representative number of variants described also supports the scope of claims 16 and 29 encompassing "variants" of "translation products of the gene coding for a cytosolic sulfotransferase family 4A member 1". The specification of the instant application discloses in detail two splice variants of sulfotransferase, sv1 and sv2. For example, these splice variants are discussed on pages 30 through 33 and data thereon is presented in Figures 4-11 and 15-17 of the published international application WO 2005/030947.

Applicants maintain that studies on a representative number of animals are described in the specification of the instant application to support the scope of claims 12-13 encompassing a range of test animals. For example, the generation of transgenic mice is described on pages 45-47, and the generation of transgenic Drosophila flies is described on pages 47-51 of the published international application WO 2005/030947. Experiments performed on flies are discussed, for example, on pages 35-36 and data presented in Figures 22-25. Applicants disclose an enabling example of a screening assay in the second full paragraph on page 25. Applicants disclose an enabling example of a screening assay using human neuroglioma cells in Examples (v) (immunofluorescence analysis) and (vi) (cytotoxicity/viability assay) on pages 44-45 and in Figures 18 and 19. The animal and cell culture systems described represent a wide range of complexity in the models used for experimental studies.

For these reasons, Applicants maintain that pending and amended claims 11-13, 16, and 29 are fully supported by the specification of the application as filed. That is, variants of substances

(i)-(iii) and the testing of compounds in animals are described. Therefore, Applicants respectfully request that the rejection of claims 11-13, 16, and 29 be withdrawn.

On page 9 of the Office Action, the Examiner states that claims 11-12, 16, 25-26, and 29 stand rejected under 35 U.S.C. § 102(b) as being anticipated by the published international application WO 2002/018541 of Farb et al. (herein, "Farb"). Applicants respectfully traverse.

Applicants have cancelled claims 25 and 26, rendering their rejection moot.

Farb does not teach each and every limitation of pending claims 11-12, 16, and 29 and, therefore, does not anticipate these claims of the instant application.

The claims on pages 40-41 of Farb cited by the Examiner are directed to methods for identifying or inhibiting "nervous system-specific sulfonation" (Farb claims 5-7) and a method for "treating a neurological disorder ... comprising administering ... a nervous system-specific sulfotransferase polypeptide [that] is an effector of nervous system-specific sulfonation" (Farb claims 8-9). That is, pages 40-41 of Farb are not directed to "[a] method for screening for a modulator of Alzheimer's disease", claimed in amended claims 11-12, 16, and 29 of the instant application.

Applicants have reviewed Farb, and were unable to find a teaching of a screening method for a modulator of Alzheimer's disease.

Farb does not disclose "(a) contacting a cell with a test compound" as required by claims 11 and 16. Farb does not disclose "(a) administering a test compound to a test animal" as required by claims 12 and 29.

Furthermore, Farb does not disclose "(b) measuring the activity and/or level of one or more substances" or "(c) measuring the activity and/or level of one or more substances ... in a control cell" as required by claims 11 and 16 of the instant application. Farb does not disclose "(b) measuring the activity and/or level of one or more substances" or "(c) measuring the activity and/or level of one or more substances ... in a matched control animal" as required by claims 12 and 29 of the instant application.

For a reference to be anticipatory, it must teach each and every element of a claim. As described above, Farb does not teach each and every element of any of amended claims 11-12, 16, and 29 of the instant application. Therefore, Farb does not anticipate any of these claims, and Applicants respectfully request that the rejection of claims 11-12, 16, and 29 be withdrawn.

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Applicants maintain that, for the reasons given above, all pending claims not withdrawn, claims 11-13, 16, and 29, are patentable and that, as such, the present application is in condition for allowance.

If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is hereby invited to telephone the undersigned at the number provided.

Applicants respectfully request that a Notice of Allowance of all pending claims 11-13, 16, and 29 be timely issued in this case.

Respectfully submitted,



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